

REMARKS

This Response to the non-final Office Action mailed June 6, 2005. Claims 1 to 55 were pending previously in the application. Of those claims, Claims 37 to 52 have withdrawn from consideration. Claims 1 to 36 and 53 to 55 have been amended herein. No new matter has been introduced by way of any of the amendments or additions. Please charge Deposit Account No. 02-1818 for any fees owed.

In the Office Action, the election/restriction requirement was removed for Claims 8 to 12, 14 to 17 and 23 to 26. Applicants thank the Examiner for reconsidering the election/restriction.

Claim 21 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The claim has been amended to recite that a different cross sectional area of the second section in combination with the same amount of fluid flowing through the sections causes different fluid velocities in the sections. The amount of fluid entering the container is the same amount that leaves the container. Different cross-sectional areas for the same volume of fluid flowing through the sections will cause different fluid velocities. Support for different cross-sectional areas is found for example at Fig. 5C and associated text ("depths" of fluid passages different).

Claims 1 to 3, 4, 7, 8 to 12, 13, 14 to 26, 27, 28, 29, 54 and 55 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,875,282 to Jordon et al. ("*Jordan*") or by U.S. Patent No. 3,475,590 to Pins ("*Pins*") in view of U.S. Application 2002/0096984 to Konishi ("*Konishi*"), U.S. Patent No. 6,261,261 to Gordon ("*Gordon*"), or U.S. Application 2003/0004470 to Hickerson ("*Hickerson*").

Claims 1 to 3, 5 to 7, 13, 18, 19, 27 to 36 and 53 were rejected under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 5,271,086 to Kamiyama et al. ("*Kamiyama*").

Regarding the rejection of independent Claims 1, 8, 13, 14, 18, 23, 27 and 30 in view of *Jordan*, *Pins*, *Konishi* and *Hickerson*, Applicants respectfully submit that the claims as presently presented are patentably distinguished over those references. In general, the claims are now directed not simply to a heater but to dialysis machines or devices having at least one other dialysis machine component operating in combination the specified heater. Support for the additional dialysis components can be found for example in connection with Fig. 6 and accompanying disclosure. Support for the positioning of the heaters relative to a disposable cassette can be found for example in connection with Figs. 1, 2 and 5A to 5C and associated text.

Claim 1

Claim 1 for example is directed to a medical fluid device including: (i) an enclosure housing a medical fluid pump; (ii) a radiant heater that emits energy in a direction towards the fluid pumped by the pump; (iii) a secondary heater that emits energy in a direction towards the fluid pumped by the pump; (iv) the radiant heater and secondary heater housed by the enclosure so that a disposable fluid cassette can be positioned with respect to the enclosure to be heated by the radiant and secondary heaters; and (v) a controller that causes one of the infrared heater and the secondary heater to be powered at a first time and both the infrared heater and the secondary heater to be powered at a second time to maintain a desired temperature of the fluid pumped by the pump.

No reference discloses or teaches such a medical fluid machine with a pump and heater configured to move and heat medical fluid in the claimed manner. For example, *Hickerson* in Fig. 1 discloses a pump 22 and temperature elements 6 that contact a cartridge 19. Cartridge 19 in Fig. 2 has a pumping mechanism 23 and “shaped protrusions 24 with heat exchange surfaces that interface with similar protrusions within the control unit 1.” [paragraph 33] The infrared heating systems of the prior art would not work with the shaped protrusions 24 of the cartridge 19 of *Hickerson*. The infrared heater of *Gordon* for example includes a solution tube 18 operable with an energy generating sheet 30, which can heat fluid within multiple turns of tube 18. Energy generating sheet 30 of *Gordon* could not be positioned to efficiently heat the multiple shaped protrusions 24 of *Hickerson*. And even if it could, there would be likely no room remaining for the secondary heater as called for in Claim 1.

As seen for example in Figs. 1, 2 and 3 of *Jordan*, the slot heater of *Jordan* is not configured to accept the multiple protrusions 24 of *Hickerson*. Likewise, the triangular heater of *Pins* does not appear to be operable with the multiple protrusions 24 of *Hickerson*. Further, *Hickerson* provides no suggestion to use its cartridge 19 with the tubular lamp of *Konishi*. Instead, *Hickerson* advocates mating sheet-like temperature elements 6 that contact mating sheet-like protrusions 24 of *Hickerson*. One skilled in the art would not therefore be motivated to combine the structural teachings of *Hickerson* with any of the heaters of *Jordan*, *Pins*, *Konishi* and/or *Gordon*.

Moreover, there is no disclosure in *Hickerson* to suggest that the elements are separate heaters that are separately controllable as called for by Claim 1. The only references cited for multiple heaters are *Jordan* and *Pins*. As discussed in the previous Response, neither *Jordan* nor *Pins* teaches the specified heater control of Claim 1. For example, *Jordan* at column 5, line 5 states that energy transferred is accomplished by conduction, convection and radiation from heater plates, on both sides, to the disposal bag. [Emphasis added]. This statement suggests that *Jordan* cannot supply power at a first time from one of the heater plates and at a second time from both of the heater plates. The Office Action states that *Jordan* suggests varying the heating from one heater to both heaters but cites no supporting passage in *Jordan*. Applicants can find no suggestion to vary the heat between one or both heaters. It is debatable whether *Jordan* even teaches separately powered heaters. *Jordan* seems to teach instead that both heaters are powered the same, although variably the same.

Likewise, Fig. 5 of *Pins* shows an electrical diagram and illustrates heaters 16 and 18 placed in parallel with respect to each other. The circuit does not appear to provide for the ability to power only one heater at a first time and to power both heaters at a second time. This assertion was not rebutted in the Office Action.

Regarding *Kamiyama*, that reference appears to disclose, teach or suggest only a single heater, namely, tubular ceramic heater 4. That singular heater heats a first quartz glass tube 5, a second quartz glass tube 6 and a third quartz glass tube 7. Accordingly, *Kamiyama* does not teach or suggest a radiant heater and a secondary heater as called for in Claim 1. *Kamiyama* cannot therefore disclose, teach or suggest a controller that causes one of the infrared heater and a secondary heater to be powered at a first time and both the infrared heater and the secondary heater to be powered at a second time to maintain a desired temperature of the fluid as set forth in Claim 1.

Further, the heater of *Kamiyama* is also not configured to be operable with the multiple shaped protrusions 24 of *Hickerson*. One skilled in the art would not be motivated to combine the structural teachings of *Hickerson* with the heater of *Kamiyama*. Applicants submit that the references alone or in combination do not disclose, teach or suggest the medical fluid device of Claim 1. Accordingly, those references do not disclose, teach or suggest dependent Claims 2 to 7.

Dependent Claim 6 provides additional patentable subject matter over *Jordan*, *Pins*, *Hickerson* and *Kamiyama*. As discussed above, *Hickerson* and *Kamiyama* disclose only a single heater. *Jordan* and *Pins* both illustrate their respective dual heaters in a parallel relationship on two sides of the fluid to be warmed. Accordingly, none of those references teaches or suggests placing the secondary heater fluidly upstream of the infrared heater or fluidly downstream of the infrared heater as spelled out in Claim 6. Support for the structure of Claim 6 can be found for example at page 12, line 29. Claim 6 is therefore patentable independently over those references. No attempt to rebut the patentability of Claim 6 is made in the present Office Action.

Claim 8

Claim 8 is directed to a medical fluid therapy device for flowing fluids through a disposable dialysis unit. The device includes: (i) an enclosure configured to removably accept the disposable unit; and (ii) an infrared heater having an infrared emitter positioned in a housing, the housing positioned within the enclosure and defining an opening facing the disposable unit when the unit is installed in the enclosure, the infrared heater having an infrared transmissive material covering the opening, and the infrared heater having an infrared reflector positioned relative to the infrared emitter such that infrared energy from the infrared emitter is substantially directed toward the infrared transmissive material.

No reference discloses an enclosure in which an infrared emitter is housed, the infrared emitter having a housing defining an opening facing a disposable unit. The infrared heater of *Gordon* does not include or suggest an opening with a transmissive covering facing a disposable unit. There is no suggestion either that the infrared heater of *Gordon* to place its heater inside of an enclosure of a medical fluid therapy device. The infrared heater of *Konishi* does not include or suggest an opening with a transmissive covering that can face a disposable unit. Accordingly, the cited art does not make out a prima facie case of obviousness with respect to Claim 8 and Claims 9 to 12 depending from Claim 8.

Claim 13

Regarding independent Claim 13, Applicants respectfully submit that the cited references do not alone or in combination disclose, teach or suggest that claim. As discussed above, *Kamiyama*, *Konishi* and *Hickerson* disclose only a single heater 4 and therefore cannot teach Claim 13, which includes an infrared emitter and a plate heater.

Claim 13 specifies a device for flowing a fluid through a disposable unit for dialysis treatment to a patient. The device includes: (i) an enclosure housing a fluid pump and configured to removably receive the disposable cassette; (ii) an infrared emitter so constructed and arranged with respect to the enclosure to heat at least a portion of the fluid in the disposable unit when the fluid is pumped by the pump; (iii) a plate heater so constructed and arranged with respect to the enclosure to heat at least a portion of the fluid in the disposable unit when the fluid is pumped by the pump; and (iv) a controller that causes at least one of the infrared emitter and the plate heater to achieve a desired fluid temperature.

As discussed above, one skilled in the art would not be motivated to combine the structural teachings of *Hickerson* with any of the heaters of *Jordan*, *Pins*, *Konishi*, *Kamiyama* and/or *Gordon*.

Further, neither *Pins* nor *Gordon* disclose an infrared emitter. Both references disclose the provision of electrical resistance heaters and do not disclose, teach or suggest the inclusion of an infrared emitter. Indeed, those references only mention radiant energy in passing. *Jordan* at column 5, line 5 mentions that energy transfer is accomplished by conduction, convection and radiation from heater plates. The heater plates 92 of *Jordan* are taught to include silicone rubber and to be vulcanized to the energy reservoirs 88 and 90 (*Jordan* at column 7, line 23). *Jordan* does not disclose, teach or suggest the inclusion of an infrared emitter. Likewise, *Pins* briefly mentions at column 5, line 18 that there is some heating by radiant heat from the sidewalls of block 11. Heaters 16 and 18 of *Pins* however are clearly taught to be electrical heaters (*Pins* at column 4, line 70), not infrared emitters.

Accordingly, none of the references teaches a combination infrared emitter and a plate heater for in-line heating of a fluid through a disposable dialysis unit in a device for flowing a fluid through the disposable unit.

Claim 14

Claim 14 is patentable for all the same reasons described above for Claim 13. Further, Claim 14 includes an infrared transmissive material disposed between the infrared emitter and adjacent the at least one flexible membrane of the cassette, providing a further structural reason for patentability. Applicants accordingly respectfully submit that Claim 14 and Claims 15 to 17 depending from Claim 14 are patentable over the cited art.

Claim 18

Referring now to Claim 18, none of the cited references discloses the claim as presently presented. Claim 18 is directed to a device for flowing a dialysis fluid, which includes: (i) an enclosure housing a pump and configured to removably receive a fluid container; (ii) a radiant energy heater housed by the enclosure that heats at least a first section of the fluid container, the radiant energy heater having a radiant energy emitting bulb and an apparatus that aids in directing radiant energy in a direction towards the first section; and (iii) a second heater housed by the enclosure heats at least a second section of a fluid container, the second heater having a heat transfer emission towards the second section, wherein the dialysis fluid is pumped through the container by the pump and is heated by at least one of the radiant energy heater and the second heater when the dialysis fluid is moving through the container.

As discussed above, one skilled in the art would not be motivated to combine the structural teachings of *Hickerson* with any of the heaters of *Jordan*, *Pins*, *Konishi*, *Kamiyama* and/or *Gordon*.

Also, none of the references discloses a radiant energy heater having a radiant energy emitting bulb and an apparatus that aids in directing radiant energy in a direction towards the first section.

Claim 18 and its dependants are respectfully submitted therefore to be patentable at this time. Further, as described in the previous Response, various claims depending from Claim 18 also recite patentable subject matter.

Claim 23

As discussed above, one skilled in the art would not be motivated to combine the structural teachings of *Hickerson* with any of the heaters of *Jordan*, *Pins*, *Konishi*, *Kamiyama* and/or *Gordon*.

Further, no reference discloses first and second heaters configured to heat at least about 2 liters of the dialysis fluid from about 10°C to about 37°C in about 13 minutes. A *prima facie* case of obviousness is not present. Applicants respectfully submit that Claim 23 and Claims 24 to 26 depending from Claim 23 are allowable at this time

Claim 27

Regarding Claim 27, as discussed above, one skilled in the art would not be motivated to combine the structural teachings of *Hickerson* with any of the heaters of *Jordan*, *Pins*, *Konishi*, *Kamiyama* and/or *Gordon*.

Further, the claim as presently presented specifies a second heater of a different type than the radiant heater, which heats at least a portion of the dialysis fluid traveling along the fluid flow path. As discussed above, *Kamiyama* discloses only one heater. While *Jordan* and *Pins* each disclose parallel heaters, the heaters are disclosed in each case to be of the same type. In particular, the heating pads 92 of *Jordan* are each specified to include silicone rubber and to be vulcanized to energy reservoirs 88 and 90 (*Jordan*, column 7, line 23). The heaters 16 and 18 of *Pins* are both disclosed to be electrical heaters. In both references, the two heaters are the same, teaching away from Claim 27. Claim 27 specifies that the second heater is of a different type than the radiant heater.

The motivation to combine references must be present in the references themselves. There is no motivation in the references to use two different types of heaters. Instead, the references disclose and therefore seem to prefer using the same type of heater. As discussed above, there is no hint of separate control of different heaters. The use of the same type of heater would enable the same power to be supplied to the different but same type of heater. It is not inherently obvious to make the structural change called for in Claim 27. Accordingly, Applicants respectfully submit that Claim 27 and Claims 28 and 29 that depend from Claim 27 are each in condition for allowance at this time.

Claim 30

Regarding Claim 30, as discussed above, one skilled in the art would not be motivated to combine the structural teachings of *Hickerson* with any of the heaters of *Jordan*, *Pins*, *Konishi*, *Kamiyama* and/or *Gordon*.

Further, Applicants respectfully submit that the art of record does not teach or suggest a temperature sensor coupled operably to a controller and having a signal indicative of a temperature of a dialysis fluid, wherein the controller is operable with the temperature sensor to cause power to one of the radiant energy heater or the second heater to be varied as needed. *Pins* and *Jordan* alone or in combination do not appear to disclose Claim 30 as presently presented.

Pins discloses a thermostat control, wherein a control thermostat 31 is opened when end anchors 38 and 39 move away from each other. The separation of end anchors 38 and 39 causes an actuating member to flatten and ultimately pull a contact 36 away from engagement contact 37 (*Pins*, column 4, lines 29 to 35). A second thermostat 41 is a safety thermostat (*Pins*, column 5, lines 38). Notably, there does not appear to be any suggestion in *Pins* of varying power to the heaters 16 and 18.

Jordan at column 8, line 12 appears to teach an adjustment of power to the energy reservoir. There is no disclosure or suggestion however that power to only one reservoir is varied. That is, heater elements 92 appear to be controlled the same, and there is no disclosure that power to only one reservoir is varied. *Jordan* does not disclose, teach or suggest independent power control for only one heater at a particular time. Applicants accordingly respectfully submit that Claim 30 and Claims 31 to 36 depending from Claim 30 are patentably distinct over *Pins*, *Jordan* and *Kamiyama*. Applicants also respectfully submit that *Pins*, *Jordan* and *Kamiyama* do not teach or suggest various ones of the dependent Claims 31 to 36. The Office Action does not show where the apparatuses of Claims 31 to 36 are found in *Pins*, *Jordan* and *Kamiyama*.

Amendments have been made to each of the dependent claims so that they recite a proper preamble. None of those amendments has been made for any reason related to patentability, to disclaim any subject matter or to distinguish over the prior art.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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